

Exhibit 60

缬沙坦残留溶剂未知峰研究报告
Study Report of Unknown Peak in
Residual Solvent of Valsartan

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编写部门 Preparation Dept. 川南化验室
Chuannan QC

保管部门 Archiving Dept. 川南化验室
Chuannan QC

 **浙江华海药业股份有限公司**
ZHEJIANG HUAHAI PHARMACEUTICAL CO.,LTD.



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文件变更历史

Document Change History

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1	2018.05.31	本文件为新订/Newly drafted
2	2018.06.04	诺华新增批次的残留溶剂未知峰进行定量汇总 和补充评估 The unknown peaks in residual solvent of newly added batches as per Novartis requirement are quantitatively summarized and supplemented.



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报告审批表

Review and Approval for Report

部门 Dept.	姓名/职务 Name & Title	职能 Role	签名/日期 Signature & Date
川南化验室 Chuannan QC	王俊/高级主管 Wangjun/ Senior Supervisor	编写报告 Prepare report	 2018.06.04 Wangjun 2018.06.04
川南化验室 Chuannan QC	唐银华/分析总监助理 Tang Yinhua/ Assistant of QC Director	审核 正确性和完整性 Review accuracy and completeness	 2018.06.04 Tang Yinhua 2018.06.04
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一、概述/Introduction

华海药业已于 2018 年 05 月完成对缬沙坦残留溶剂（甲醇、乙醇、乙酸乙酯、甲苯）检测方法项下的多个未知峰的研究，本次根据诺华客户的要求，对诺华新增的其他相关批次的残留溶剂未知峰进行定量汇总和升版补充评估。

The study of unknown peaks that tested residual solvent (methonal, ethanol, ethyl acetate, toluene) of Valsartan with Huahai method was completed in May 2018, and the unknown peaks in residual solvent of newly added batches as per Novartis requirement are quantitatively summarized and supplemented.

二、目的/Purpose

为评估诺华新增批次（具体批次见表 1）的未知溶剂峰的残留情况，并通过定量分析，评估其产品质量有无风险。

In order to evaluate the residual level of unknown solvent peaks for the newly added batches ((For detailed batches, please refer to Table 1) as per Novartis requirement, and to evaluate the impact on product quality through quantitative analysis.

序号 S.N	批次 Batch No.	序号 S.N	批次 Batch No.
1	C5355-18-009M	7	C5355-18-020M
2	C5355-18-010M	8	C5355-18-028M
3	C5355-18-011M	9	C5355-18-029M



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序号 S.N	批次 Batch No.	序号 S.N	批次 Batch No.
4	C5355-18-012M	10	C5355-18-030M
5	C5355-18-013M	11	C5355-18-031M
6	C5355-18-019M	12	C5355-18-033M

表 1（诺华要求涉及批次）

Table 1 Involved batches required by Novartis

三、定量分析/ Quantification

为确定缬沙坦中二氯甲烷、甲基叔丁基醚（MTBE）、异丁醛、正己烷、乙酸异丙酯、丙酸乙酯、乙酸丙酯的残留情况，对相应批次的原先放行图谱中的未知峰进行重新积分处理，通过定位图谱中 60ppm 的二氯甲烷峰面积 13；500ppm 的甲基叔丁基醚（MTBE）峰面积 2036；500ppm 的异丁醛峰面积 111；29ppm 的正己烷峰面积 352；500ppm 的乙酸异丙酯、丙酸乙酯、乙酸丙酯峰面积 437、324、279 进行计算（定位图谱峰面积汇总见表 2，定位图谱详见附件 1），诺华新增批次未知峰的残留结果详见表 3（供试品图谱详见附件 2）：

In order to determine residue level of dichloromethane, MTBE, isobutyraldehyde, n-hexane, isopropyl acetate, ethyl propionate and propyl acetate, re-integration has been performed for the unknown peaks in the original released chromatogram of the corresponding batches. Based on the peak area of solvents of different ppm in the identification reference chromatogram, where peak area of dichloromethane (60ppm) is 13, peak area of



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Isobutyraldehyde has been identified. N-hexane may be introduced by trace residue of solvent. The unknown peaks in residual solvent of Valsartan are far lower than the ICH limit of each solvent through quantitative analysis. The product quality is less likely to be impacted.

五、结论/Conclusion

综上所述，华海药业生产的缬沙坦产品其残留溶剂未知峰的残留量均远远低于各溶剂指标要求，对产品质量无风险。

From the above, the unknown peaks in residual solvent of Valsartan manufactured by Huahai are far lower than the limit of each solvent. The product quality is less likely to be impacted.